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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,097	10/27/2003	James D. Hughett	0341-0003.15	3110

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Mark J. Murphy
Cook, Alex, McFarron, Manzo,
Cummings & Mehler, Ltd.
200 West Adams St., Ste. 2850
Chicago, IL 60606

EXAMINER

VENIAMINOV, NIKITA R

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,097

Applicant(s)

HUGHETT ET AL.

Examiner

Nikita R Veniaminov

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date see OA.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 10/27/2003 has been considered by the examiner.

Claim Objections

2. Claim 14 is objected to because of the following informalities: Claim 14 should depend from Claim 13. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 12 the phrase "by means of" in line 4 causes confusion as to whether 35 U.S.C. 112, sixth paragraph is been invoked.

Claim Rejections - 35 USC § 102

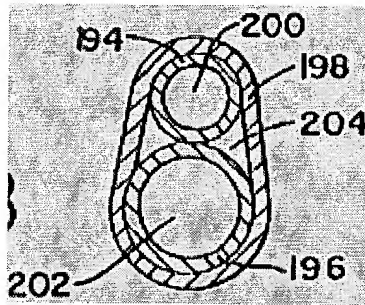
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 12 and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Waksman et al. (US 6,306,074 B1). Waksman et al. ('074) teach a catheter having a proximal end and a distal end for use in a intraluminal treatment system, wherein a treating element is advanced from the proximal end of the catheter to the distal end by means of pressurized fluid, the catheter comprising: first, second, third and fourth lumens extending substantially from the proximal end to the distal end of the catheter, the first lumen 202 being sized to slidably receive the treating element but to prevent the treating element from exiting the first lumen at the distal end of the catheter, the first lumen being in fluid communication with the second 204 and third 204 lumens at the distal end

thereof, and the fourth lumen 200 being open at the distal end and sized to



receive a

guidewire (see Figures 7A and 7B; abstract and column 17, lines 20-46); wherein the proximal and distal ends of the catheter are of different stiffness and flexibility, and the distal end has a cross-sectional area smaller than the proximal end of the catheter and a non-circular cross-sectional shape so as to permit perfusion; wherein the proximal end is fused to the distal end (see Figures 6B and 7B). Examiner states that while Waksman et al. ('074) refer to a single return lumen, the figure illustrates two distinct spaces (lumens).

Claim 17 is written as product-by-process, structurally it is not distinguished from the catheter of Waksman et al. ('074). See MPEP, Section 2113 [R-1].

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over Waksman et al. (US 6,306,074 B1) in view of Brown et al. (US 6,053,900). Waksman et al. ('074) teach a catheter as described in paragraph 6 above, but they do not teach a catheter, wherein a fourth lumen includes a protective liner; and wherein the protective liner is polyimide. However, Brown et al. ('900) teach a catheter having a guide wire tube 189 placed over a guide wire 189w; said tube is formed of a polymer (see figures 31 and 32; column 20, lines 50-65). Also, Brown et al. ('900) teach a polyimide tubing (see column 24, lines 43-47), which is a polymer. It would have been obvious to one of ordinary skill in the art at the time of invention to implement the polyimide tubing of Brown et al. ('900) as a protective liner of the guidewire lumen of Waksman et al. ('074) in order to provide extra durability and lubricate the walls of said lumen for easier manipulation of the catheter of Waksman et al. ('074) over the guidewire.

The applied reference (Waksman et al. US 6,306,074 B1) has a common inventor and a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by

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submitting the statement that the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Davis et al. ('16724); Cornelius ('909); Forman et al. ('092); Lieber et al. ('016); Longton et al. ('477); Teirstein ('659); Chen et al. ('245); Pomeranz et al. ('936); Jung et al. ('853); Hastings et al. ('708); Sahatjian ('203); Sahota et al. ('653); Wantink et al. ('810) and Saab ('392).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

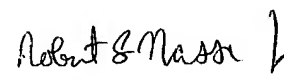
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nikita R Veniaminov
Examiner
Art Unit 3736

May 14, 2004.



ROBERT L. NASSER
PRIMARY EXAMINER